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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,293	11/03/2003	Edward Nowak	061170-0194	6240
31824 7590 01/22/2008 MCDERMOTT WILL & EMERY LLP 18191 VON KARMAN AVE. SUITE 500 IRVINE, CA 92612-7108			EXAMINER SHEIKH, HUMERA N	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 01/22/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/701,293	Applicant(s) NOWAK ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/030,902.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Response and Amendment after Non-Final Office Action and Applicant's Arguments/Remarks, all filed 11/13/07 is acknowledged.

Claims 15-52 are pending in this action. New claims 51 and 52 have been added by the amendment of 11/13/07. Claims 1-14 were previously cancelled. Claims 15-52 remain rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51 and 52 recite the limitation "one of the two layers of material" in line 2 of each of claims 51 and 52. There is insufficient antecedent basis for this limitation in the claim.

Claims 51 and 52 appear to require 4 layers whereas claim 15 only provides a recitation of two layers. Claim 15 from which these claims depend, recite a dividing wall and a septum, each having two layers. Newly presented claim 51 recites "...one of the two layers of material...than the other of the two layers of material." Newly presented claim 52 recites parallel language.

The claims are also indefinite because it cannot be established if the claims require a dividing wall and a septum, resulting in a structure having 4 layers or a dividing wall or a septum. Claim 15, from which the claims depend, requires a single structure to be chosen. Claims 51 and 52 appear to require 4 layers.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda *et al.* (EPO 0 211 079 A1) in view of Brown (WO 97/35537) and vice versa.

The instant invention is drawn to a delivery capsule having at least two separate chambers, the capsule including a dividing wall or septum defining in part two separate chambers, wherein the dividing wall or septum comprises two layers of material adhered together with an adhesive material.

Ueda *et al.* ('079) teach a soft multi-chamber delivery capsule, process of making and an apparatus for producing the capsule, wherein the capsule consists of a covering, the inner space of which is divided into a plurality of chambers by at least one partition. The number of such chambers is usually two, and the space between the first and second coverings is divided into two chambers by a partition provided therebetween. The capsule comprises a first, second and

third film, whereby the films are joined under pressure, except their respective capsule-defining portions. The chambers contain materials, such as medicine, cosmetics or food (see Abstract).

Ueda teaches a soft capsule of novel structure, which, although single, is adapted to stably enclose at least two kinds of incompatible contents, and which can be made, for example, to have one portion of rapidly soluble or intragastrically soluble properties and the other portion of prolonged release or enteric properties, or to have one portion with a rapid release action and the other portion with a delayed release action. With the multicellular soft capsule, different contents can be enclosed in the different cells (page 2, lines 15-23).

Any material usually used for the shell of the soft capsules is usable for forming the shells and partition, such as gelatin, plasticizers, perfume, pigments, solubility, adjusting agents, etc. can be added as desired (pg. 11, lines 6-11).

The multicellular capsule may be of any shape, such as oval shape, oblong form, round form, tubular form or in the form of a suppository (pg. 11, lines 16-21).

The examples on pages 13-17 demonstrate the method of manufacturing the multicellular soft capsules.

It is noted that Ueda teaches a single film, whereas Applicants utilize two layers of material (adhered together with an adhesive material). However, it is the position of the Examiner that the soft capsules of Ueda entail a similar function and purpose as that of the instantly claimed delivery capsule. Ueda explicitly teaches a soft, divided, multi-compartmented capsule to hold various active substances that can be incompatible with each other. Moreover, Applicants have not demonstrated any significant patentable distinction between the Ueda

delivery capsule and the instant delivery capsule. The Ueda capsule would be capable of imparting effective drug delivery to a user in need thereof.

Ueda *et al.* do not explicitly teach chambers containing metered doses of materials contained within the capsule.

Brown ('537) teaches capsules comprising metered doses of substances to be encapsulated within the capsule, carried out through injection, wherein as the doses of substances are injected between the heated films, the films deform to line the indentations, forming series of pairs of opposed capsule halves containing the substance (see page 6, lines 5-19).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the capsules of Brown within the teachings of Ueda, because Brown explicitly teaches capsules that can efficiently comprise metered doses of substances contained within the capsule. The expected result would be an improved multicellular capsule comprising metered doses of varying substances for effective capsule delivery.

* * * * *

Brown ('537) discloses capsules, a method of encapsulation and an encapsulation apparatus, wherein the capsules comprise metered doses of substances to be encapsulated within the capsule, wherein as the doses of substances are injected between the heated films, the films deform to line the indentations, forming series of pairs of opposed capsule halves containing the

substance. The pairs of capsule halves are then brought together, sealed and cut, thus forming capsules containing the substance.

The method of encapsulation is characterized by supplying to an encapsulation unit, two films of like material capable of deforming elastically at least when partially solvated, and applying solvent to at least one of the films prior to encapsulation to cause partial solvation of the material surface, such that the partially solvated surface can adhere to and seal with the film material. The invention enables encapsulation-using materials other than gelatin, such as polyvinyl alcohol. Further suitable materials include alginate, hydroxypropyl methyl cellulose and polyethylene oxide, for example (see page 6, lines 5-19 and Abstract).

Brown teaches a single chamber that is not divided. Brown does not teach two separate chambers having a dividing wall or partition.

Ueda ('079) teaches a soft multi-chamber delivery capsule, process of making and an apparatus for producing the capsule, wherein the capsule consists of a covering, the inner space of which is divided into a plurality of chambers by at least one partition. The number of such chambers is usually two, and the space between the first and second coverings is divided into two chambers by a partition provided therebetween. The capsule comprises a first, second and third film, whereby the films are joined under pressure, except their respective capsule-defining portions. The chambers contain materials, such as medicine, cosmetics or food (see Abstract).

Ueda teaches a soft capsule of novel structure, which, although single, is adapted to stably enclose at least two kinds of incompatible contents, and which can be made, for example, to have one portion of rapidly soluble or intragastrically soluble properties and the other portion

of prolonged release or enteric properties, or to have one portion with a rapid release action and the other portion with a delayed release action. With the multicellular soft capsule, different contents can be enclosed in the different cells (page 2, lines 15-23).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate multi-compartments comprising a partition as taught by Ueda within the capsules of Brown. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Ueda teaches a soft multi-chamber delivery capsule containing a partition, whereby the multiple compartments function to hold at least two components or substances that can be incompatible with each other. The expected result would be an improved multi-compartmented capsule for delivering metered doses of varied active substances.

Response to Arguments

Applicant's arguments filed 11/13/07 have been fully considered but were not found to be persuasive.

Applicant argued, "Ueda is directed to a multi-chamber capsule divided into a plurality of chambers, the chambers are divided by a **single** film. More particularly, Ueda teaches a system and method in which films are deformed into cavities in a rotating drum, such that the cavities are filled when the opening to these cavities are in a vertical or substantially vertical position. See Ueda, Figure 2; p.9 ll. 7-25. Alternatively, Ueda discloses filling one cavity when the cavity is in a horizontal position, applying a septum material to the top of this cavity, applying the second filling material to the top of the septum and then applying the second capsule cavity material on top of both the septum and the second filling material. See Ueda, p. 10, 1.17 -p. 11, 1.5. Ueda's multi-chamber capsule, being divided by a single film, suffers from a number of deficiencies when compared to a delivery capsule of the claimed invention. For example, a delivery capsule of the claimed invention, comprises two capsule cavities that can be separately filled and sealed prior to being adhered together, a far more simple and efficient filling process than that of Ueda. Moreover, the two capsule cavities can be partially filled (in contrast to Ueda

and Brown, which both rely on the filling process to deform the film and create the cavities) prior to sealing and adhesion together. The partially filled delivery capsules enjoy a greater propensity for distortion of shape (e.g., "softness") such that, for example, the capsules may be more easily swallowed. Further, given the importance of the accuracy in delivery capsules, the ability to only partially fill the cavities of the claimed delivery capsules allows for metered doses.

Applicant's arguments were not persuasive. It remains the position of the Examiner that the two-layered septum film being claimed by Applicant does not patentably define and distinguish over the explicit reference teachings of the art. The capsule of Ueda is functionally equivalent to the capsule of the instant invention. Namely, the Ueda reference demonstrates a capsule having multiple compartments which function to hold different active substances. Applicant's argument that "the instant invention allows greater propensity for distortion of shape (e.g. softness) was not persuasive since the capsule of Ueda is a soft capsule which would also be easy to swallow. As noted above, the Ueda capsule functions in a similar manner as that of the instant capsule. Absent any evidence or showing of unexpected results obtained by the instant invention, the teachings of the prior art of record are sufficient to meet the limitations of the instant capsule. The claims, as presently recited, remain generic enough to read on the teachings of the combination of Ueda and Brown.

With regards to Brown ('537), Applicant argued, "Brown is not seen to remedy the foregoing deficiency of Ueda. Brown is generally directed to a method of encapsulation for forming capsules. The capsules are formed by bringing together two opposed capsule halves in the shape of open hemispheres, such that they form a single, undivided chamber. Nowhere is Brown seen to disclose or suggest a septum or a dividing wall of any kind, let alone a dividing wall or septum having two layers of material adhered together with an adhesive material."

Applicant's arguments were not persuasive. While Brown do not teach a divided capsule having more than one compartment, the Ueda reference has been relied upon for the teaching of

a soft divided capsule having multiple compartments to hold various active substances that can be incompatible with each other. Thus, the Ueda reference amply remedies this deficiency of Brown by their teaching which suggests that it is well known to formulate a capsule having more than one or multiple chambers or compartments for separation of various substances.

Newly presented claims 51 and 52 have been rejected under 112, 2nd paragraph, for being indefinite, as delineated in the Office Action (see above).

The rejections of record have been maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1618

January 10, 2008


HUMERA N SHEIKH
PRIMARY EXAMINER

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